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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAMBERTSON, DAVID A

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 03/12/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,397

Applicant(s)

BUB ET AL.

Examiner

David A Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.135(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 5, 6 and 8-13 is/are allowed.
- 6) ☒ Claim(s) 3 and 7 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of a reply, filed December 16, 2002 as Paper No. 13, to the previous Office Action. Amendments were made to the claims.

Claims 1-13 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 9, mailed July 16, 2002, that is not addressed in this action has been withdrawn.

Because all of the rejections made in this Office Action are either maintained from a previous Office Action or necessitated by amendment to the claims, this Office Action is made FINAL.

Drawings

New corrected drawings are required in this application because of the reasons set forth in the attached Draftsperson's PTO-948 form. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

A substitute specification without the claims is required pursuant to 37 CFR 1.125(a) because the specification is not recited in the proper English vernacular. Applicant's response

indicates that a substitute specification has been filed, however no such substitute has been found. It appears that applicant has simply corrected the specific examples that the Examiner has pointed out in the previous Office Action, while missing several grammatical and idiomatic issues within those very same amendments. Since these are merely examples and not a complete list of the deficiencies in the specification, this procedure is not sufficient to put the application in compliance with 37 CFR 1.52 (a). Applicant is required to submit a complete substitute specification in proper idiomatic English prior to any indication of allowance.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Additionally, a number of the amendments to the specification seem misdirected. For example, applicant appears to amend the specification to include the "Brief Description of the Drawings" beginning on page 4. At this location, applicant only describes Figure 5, while the remaining descriptions are located on page 14 of the specification. Curiously, these descriptions occur in what has been amended to become the "Detailed Description of the Invention" section. Applicant is advised to review these amendments when preparing the required substitute specification in order to address any inconsistencies with the natural flow of the specification.

Claim Objections

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, the sequence disclosed in claim 4 as SEQ ID NO: 5 is the only sequence that represents the SK primer sequence. Therefore, by specifically listing the sequence, applicant does not further limit claim 1 since no other sequence can be used in claim 1 by definition of the SK primer sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is both maintained for reasons set forth in the previous Office Action and necessitated by amendment.**

Claim 3 is rejected as being indefinite for the use of the terminology “SK primer sequence elements comprise a ‘marker’”, which is maintained for reasons set forth in the previous Office Action concerning the use of the language “marker complex”, which the Examiner finds to be substantially the same as ‘marker’. In order to further clarify the nature of the rejection, it is unclear if the ‘marker’ represents the element that is being detected (e.g., boron atom), or if the term ‘marker’ is intended to indicate something else (e.g., the repetitive sequence

of the plasmid). **This rejection is maintained for reasons set forth in the previous Office Action.**

Claims 3 and 7 are rejected as being indefinite for the use of the terminology “target structure.” This terminology is indefinite because it does not clearly set forth the metes and bounds of the claim.

On page 4, lines 19-22 of the instant specification, the plasmid comprising the repetitive SK primer sequence elements is referred to as a “target structure.” Claims 3 and 7 then claim that the plasmid (or plasmid-marker complex) binds to a “target structure.” It is unclear what the term “target structure” refers to in these claims; is it the detectable element that is being attached to the SKO (or the SKO-detectable element complex), some other structure that has not been described clearly in the specification, or is it the plasmid itself, as per the indication on page 4, lines 19-22? While the specification refers to the term “target structure” as it pertains to the plasmid comprising the repetitive SK primer sequence elements, it is unclear how this plasmid would bind to itself, suggesting that “target structure” has an additional meaning that is not clearly set forth in the instant specification. Furthermore, the method of detecting the “target structure”, as claimed in claim 7, does not appear to be the invention that is described in the specification. In particular, step c) recites “binding the plasmid-marker complex to the target structure”, but it is unclear what is being bound, and therefore what is being detected as per the method. **This is a new rejection that was necessitated by amendment.**

Response to Arguments Regarding Claim Rejections Under 35 USC § 112

Applicant's arguments filed December 16, 2002 have been fully considered but they are not persuasive. Applicant's arguments comprised the following:

1. That neither claim 3 nor the specification describes a marker complex "within" the primer sequence elements.
2. That the specification clearly defines a 'marker' (p. 5, lines 8-27) and how a marker complex is built (p.5-6, bridging paragraph)
3. That the skilled artisan would understand how a marker complex with a hybridizing element could bind a target structure during hybridization.

Applicant's arguments are not persuasive for the following reasons:

1. The claim, reading "The plasmid of claim 1, wherein the SK primer sequence elements *comprise a marker...*" can be interpreted as the SK primer element having a marker within the sequence element or where the sequence element *is* the marker, which is what renders the claim indefinite. In the absence of a clear definition of 'marker' or 'marker complex', it is unclear if the sequence itself represents the marker, or if the marker is what is being detected, in this case the detectable element (e.g., boron). Therefore, the skilled artisan would be confused as to whether the boron was in the sequence element, attached to the SKO, or whether the claim referred to the SK primer sequence element itself as the 'marker'.
2. The section of the specification to which applicant points as clearly defining 'marker complex' or 'marker', in fact offers contradictory evidence. In one aspect, the specification indicates, "A homologous sequence may be bound to this repetitive sequence (the SK elements)

by means of hybridization. In case this hybridization sequence carries a *marker complex* (suggesting that the plasmid does not comprise the marker complex), the marker will reach the target structure by hybridization" (see for example page 5, lines 8-11). In this case, which is the sequence that carries the 'marker'/'marker complex', the SKO or the plasmid? From the definition of "target structure" on page 4, lines 19-22 of the instant specification, it would appear that it is the SKO, and not the plasmid, that comprises the marker complex. However, this is in direct contradiction to the claim which indicates that the SK primer sequences (in the plasmid) comprise the marker.

This is further made unclear by the following paragraph, which goes on to describe the SKO, and its synthesis so as to comprise a marker compound (e.g., boron marker). While it would be clear to the skilled artisan from this paragraph how the SKO/marker compound is built, it is unclear how the plasmid can then *comprise* this marker complex since it appears to be a separate entity (i.e., the SKO) from the plasmid. Therefore the question remains: does the plasmid comprise the 'marker' or does the SKO plasmid comprise the 'marker'?

3. While it is agreeable that the skilled artisan would understand the basic concept of hybridization, it is unclear what and where the 'marker complex' is (as outlined in reasons 1 and 2 above). As a result, understanding the concept of hybridization would not assist the skilled artisan in understanding the invention.

In conclusion, the indefiniteness regarding claim 3 remains in the absence of a clear definition/location for 'marker'/'marker complex'. The issues that remain are: a) what is the 'marker complex'- the SK primer sequence element itself, or the detectable element, because both are referred to as markers; and b) what comprises the marker complex, the SKO or the SK

primer sequences of the plasmid. From the definitions in the instant specification and the terminology used in the instant claims, it would appear that the SKO comprises the marker complex, and not the plasmid. Although this is not part of the maintained rejection, it is worth noting that the use of the term target structure further confuses the relationship between the marker and the plasmid. Amendments to the claims that would better indicate these properties in the claims are required to further prosecution of this application in light of the above arguments.

Allowable Subject Matter

Claims 1, 2, 5, 6 and 8-13 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
March 10, 2003

DAVID GUZO
PRIMARY EXAMINER
